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EXAMINER

BERHANU, ETSUB D

ART UNIT PAPER NUMBER

3768

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/824,387

Applicant(s)

BAE ET AL.

Examiner

Etsub D. Berhanu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/8/04 1/25/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 10, 11, 31 and 32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 10 and 31 include a waveguide installed near an eardrum as part of the claimed subject matter. It is suggested that line 3 of claims 10 and 31 be amended to include the phrase “adapted to be/configured to be” to eliminate human tissue as part of the invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 9-11, 15, 19, 42, 43, 47 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulze et al.'692 (cited by examiner).

Figure 2 of Schulze et al.'692 discloses an apparatus for measuring a bio signal comprising: a bio signal measurement unit 20 insertable into an ear (col. 7, lines 7-18); a photoplethysmography (PPG) measurement module 22; a control unit having a PPG signal processor 58; light source units 34 and 36 of different wavelengths (col. 4, lines 26-30); photodetector 32; a temperature measurement module 26 and a temperature processor 28; and mobile communication circuitry 30 which is capable of wirelessly transmitting bio information to a display 120 (Figure 12) located at a predetermined medical institution

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(col. 9, lines 39-47). Schulze et al.'692 also discloses that the bio signal measurement unit comprises optical fiber waveguides (col. 4, lines 9-21).

Regarding claims 4-6, Schulze et al.'692 discloses that the external processor 24 of the apparatus described in paragraph 4 above is capable of determining a heart rate by measuring the time between peaks of an electrical signal generated by the photodetector 32 (col. 4, lines 58-60), and capable of determining a respiration rate (col. 4, line 61 – col. 5, line 7).

Schulze et al.'692 further discloses a method of measuring a bio signal using an ear type bio signal measurement apparatus, the method comprising: receiving infrared rays radiated from the tympanic membrane and measuring a body temperature (col. 3, lines 36-45); radiating light having different wavelengths onto an internal surface of an ear, receiving light transmitted through the ear and measuring oxygen saturation, heart rate and respiration (col. 4, lines 26-62); and outputting a bio signal measured (col. 9, lines 39-47). The method further includes detecting peaks of the PPG signal, generating bio information using the detected peaks and measuring a pulse rate using a time interval between peaks of the PPG signal (col. 4, lines 57-60). Col. 3, line 63 – col. 4, line 2 and lines 45-62 of col. 4 indicate that external processor 24 is capable of being programmed to execute the method described above.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 7 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692, as applied to claims 1 and 43 above, and further in view of Mendelson'558 (US Pub. No. 2002/0042558).

Schulze et al.'692 discloses all the elements of the current invention, as discussed in paragraph 4, except for the signal processor comprising a reflection coefficient detector and an oxygen saturation detector for detecting oxygen saturation in blood using a ratio between reflection coefficients of the different wavelengths, and a method of detecting an AC component and a DC component from each of PPG signals detected at the different wavelengths and measuring reflection coefficients of the different wavelengths and calculating oxygen saturation in blood using a ratio between the reflection coefficients of the different wavelengths.

Schulze et al.'692 also discloses that the technique of using signals relating two different wavelengths to determine oxygen saturation is well known in the art, one such technique based on the recognition that the difference in signals related to the reflection of light at two different wavelengths can be used to determine oxygen saturation (col. 5, lines 26-35).

Mendelson'558 teaches the technique mentioned in Schulze et al.'692 with the use of a pulse oximeter reflectance sensor to detect an AC component and a DC component of a PPG signal, and then calculate an oxygen saturation value in blood using a ratio between the reflection coefficients of the different wavelengths (page 5, section [0073]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Schulze et al.'692 to include detecting an AC component and a DC component from each PPG signal, measure reflection coefficients of the different wavelengths, and calculate oxygen saturation in blood using a ratio between the reflection coefficients of the different wavelengths, as taught by Mendelson'558, since the method described by Mendelson'558 meets the criteria of the oxygen saturation determination technique mentioned in Schulze et al.'692.

7. Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692, as applied to claim 1 above, and further in view of Nedivi'060 (US Patent No. 5,002,060).

Schulze et al.'692 discloses all the elements of the current invention, as discussed in paragraph 4, except for the PPG signal processor further comprising an amplifier and filter, and the temperature processor further comprising an amplifier, filter and analog-to-digital converter.

Nedivi'060 teaches the use of sensor means adapted to detect respiration and a heart beat, comprising an amplifier, filter and analog-to-digital converter, in order to digitize a signal to be applied to a digital signal processor (col. 2, lines 26-38).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the PPG signal and temperature processors of Schulze et al.'692 to include an amplifier, filter and analog-to-digital converter, as taught by Nedivi'060, since it would allow the bio signals measured to be digitized before being sent to the external processor (col. 4, lines 42-44 of Schulze et al.'692 indicate that digital data is sent to the external processor for further processing).

8. Claims 13, 14, 17, 18, 21-27, 30-32, 34-36, 38-40 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692, as applied to claim 1 above, and further in view of Uchida et al.'829 (US Patent No. 6,078,829).

Schulze et al.'692 discloses all the elements of the current invention, as discussed in paragraph 4, except for: the output unit being a liquid crystal display apparatus, the apparatus containing an earphone connected to the control unit, wherein the earphone has a speaker and the control unit has a sound processor.

Figure 1 of Uchida et al.'829 teaches the use of a light-weight liquid crystal display apparatus 9, wherein the apparatus contains a mobile communication terminal, attached to a biological measurement apparatus 1 to allow a user to be able to view biological information output without burden (col. 4, lines 33-34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the output unit of Schulze et al.'692 to include a light-weight liquid crystal display, as taught by Uchida et al.'829, since it would allow a subject to view output data conveniently without burden.

Uchida et al.'829 also teaches the use of an earphone with a plurality of electrodes on an outer surface (Figure 2), and a speaker and acoustic signal control unit to convert biological information computed in a processor into acoustic signals and forward those signals to the speaker so that biological information is sent to a subject in the form of a prerecorded message in an artificial human voice in the event that a pulse rate calculated by the signal processor exceeds a threshold value (col. 5, lines 29-42).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Schulze et al.'692 to include an earphone connected to the control unit, as taught by Uchida et al.'829, since it would allow prerecorded messages to be sent to the subject when a calculated pulse rate exceeded a specific level.

9. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692 further in view of Uchida et al.'829, as applied to claim 22 above, and further in view of Mendelson'558.

Schulze et al.'692 further in view of Uchida et al.'829 discloses all the elements of the current invention, as discussed in paragraph 8, except for the signal processor further comprising a reflection coefficient detector and an oxygen saturation detector for detecting oxygen saturation in blood using a ratio between reflection coefficients of the different wavelengths.

Schulze et al.'692 also discloses that the technique of using signals relating two different wavelengths to determine oxygen saturation is well known in the art, one such technique based on the recognition that the difference in signals related to the reflection of light at two different wavelengths can be used to determine oxygen saturation (col. 5, lines 26-35).

Mendelson'558 teaches the use of a pulse oximeter reflectance sensor to detect an AC component and a DC component of a PPG signal, and then calculate an oxygen saturation value in blood using a ratio between the reflection coefficients of the different wavelengths (page 5, section [0073]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the signal processor of Schulze et al.'692 further in view of Uchida et al.'829 to include a reflection coefficient detector for detecting an AC component and a DC component from each of PPG signals detected at different wavelengths and measuring reflection coefficients, and an oxygen saturation detector for detecting oxygen saturation in blood using a ratio between the reflection coefficients, as taught by Mendelson'558, since it would allow oxygen saturation in blood to be determined using the technique mentioned in Schulze et al.'692.

10. Claims 29 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692 further in view of Uchida et al.'829, as applied to claim 22 above, and further in view of Nedivi'060.

Schulze et al.'692 further in view of Uchida et al.'829 discloses all the elements of the current invention, as discussed in paragraph 8, except for the PPG signal processor further comprising an amplifier and filter, and the temperature processor further comprising an amplifier, filter and analog-to-digital converter.

Nedivi'060 teaches the use of sensor means adapted to detect respiration and a heart beat, comprising an amplifier, filter and analog-to-digital converter, in order to digitize a signal to be applied to a digital signal processor (col. 2, lines 26-38).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the PPG signal and temperature processors of Schulze et al.'692 further in view of Uchida'829 to include an amplifier, filter and analog-to-digital converter, as taught by Nedivi'060, since it would allow

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the bio signals measured to be digitized before being sent to the external processor (col. 4, lines 42-44 of Schulze et al.'692 indicate that digital data is sent to the external processor for further processing).

11. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692, as applied to claim 43 above, further in view of Dekker'054 (US Pub. No. 2003/0163054).

Schulze et al.'692 discloses all the elements of the current invention, as discussed in paragraph 4, except for the method comprising band-pass filtering the PPG signal to detect a respiration frequency.

Dekker'054 teaches band-pass filtering a PPG signal to provide a fast, robust and computationally efficient mechanism for noninvasively monitoring patient respiration (page 2, section [0012]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Schulze et al.'692 to include band-pass filtering the PPG signal, as taught by Dekker'054, since it would provide a faster and more computationally efficient method for noninvasively monitoring patient respiration.

12. Claims 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692, as applied to claims 1 and 9, and further in view of Cosentino et al.'705 (US Patent No. 6,454,705).

Schulze et al.'692 discloses all the elements of the current invention, as discussed in paragraph 4, except for the output unit comprising a liquid crystal display apparatus of a compact disc player.

Cosentino et al.'705 teaches the use of a computer system comprising a compact disc player and LCD monitor that is capable of being used with remote home monitoring apparatus' (col. 9, lines 30-34) to display cardiac information.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the computer system of Cosentino et al.'705 for the remote output unit of Schulze et al.'692, as it is generally held to be within the skill of the art to substitute alternate equivalent expedients.

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13. Claims 37 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692 further in view of Uchida et al.'829, as applied to claims 22 and 30 above, and further in view of Cosentino et al.'705.

Schulze et al.'692 further in view of Uchida et al.'829 discloses all the elements of the current invention, as discussed in paragraph 8, except for the output unit comprising a liquid crystal display apparatus of a compact disc player.

Cosentino et al.'705 teaches the use of a computer system comprising a compact disc player and LCD monitor that is capable of being used with remote home monitoring apparatus' (col. 9, lines 30-34) to display cardiac information.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the computer system of Cosentino et al.'705 for the remote output unit of Schulze et al.'692, as it is generally held to be within the skill of the art to substitute alternate equivalent expedients.

14. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692, as applied to claim 42 above, and further in view of Diab'741 (US Patent No. 6,816,741).

Schulze et al.'692 discloses all the elements of the current invention, as discussed in paragraph 4, except for the method comprising band-pass filtering the PPG signal collected for a predetermined period of time, detecting an inflection point by differentiating the filtered PPG signal and storing the inflection point as a peak when the inflection point has a value exceeding a predetermined threshold value.

Diab'741 teaches band-pass filtering a PPG signal, detecting an inflection point by differentiating the peaks and valleys of the filtered PPG signal, and storing the inflection point as a peak when the inflection point has a value exceeding a predetermined threshold value in order to eliminate signals corresponding to motion (col. 5, lines 3-12 and col. 6, lines 8-22).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Schulze et al.'692 to include band-pass filtering the PPG signal, detecting an

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inflection point and storing the inflection point as a peak if it exceeded a predetermined threshold value, as taught by Diab'741, since it would eliminate signals corresponding to motion.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDB


ERIC F. WINAKUR
PRIMARY EXAMINER